

AMENDMENTS

IN THE CLAIMS

1. **(Previously Amended)** A ~~drug delivery and dilution~~ device comprising:
an elongate body comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a passageway lumen in the elongate body, said lumen extending between the proximal and distal ends; and
a diffuser element operatively associated with the elongate body so as to define a diffusion space, wherein the elongate body distal end outlet is disposed in and in fluid communication with the diffusion space, and wherein the diffuser element is drug-permeable and water-permeable to provide for dilution of a drug in the diffusion space is in fluid communication with the elongate body passageway;
~~wherein, in use, a drug at a first concentration is introduced into the elongate body inlet, moves through the elongate body passageway, out the elongate body outlet, and into the diffusion space, and further wherein fluid from the environment outside the device passes into the diffusion space through the diffuser element, wherein the fluid mixes with the drug, thereby diluting the drug to a second concentration within the diffusion space,~~
~~and wherein said diluted drug then diffuses out through the diffuser element to exit the device.~~
2. **(Currently Amended)** The device of claim 1, wherein the diffuser element comprises a material selected from the group consisting of a semipermeable semipermeable membrane, a microporous membrane ~~and or~~ an ion exchange membrane.
3. **(Canceled)**
4. **(Currently Amended)** The device of claim 1, wherein the distal outlet of the elongate body is defined by an exit orifice of a drug delivery device ~~having a and the~~ diffuser element ~~provided as is~~ a cap attached to in which the exit orifice is disposed.

5. (Canceled)

6. (Original) The device of claim 1, wherein the diffusion space is defined by an outer wall of the elongate body and an inner wall of the diffuser element.

7. (Currently Amended) The device of claim 1, wherein said diffuser element ~~envelops~~ surrounds at least a portion of said elongate body.

8. (Original) The device of claim 1, wherein the diffuser element is microporous.

9. (Original) The device of claim 1, wherein the diffuser element is a dense membrane.

10. (Original) The device of claim 1, wherein the diffuser element is an ion-exchange membrane.

11. (Currently Amended) The device of claim 1, wherein ~~said a~~ diffuser element distal end extends distally beyond the elongate body distal end.

12. (Original) The device of claim 1, wherein the diffuser element is ring-shaped element.

13. (Currently Amended) The device of claim 1, wherein the diffuser element is selectively permeable to water ~~substantially impermeable to biological fluids or components of biological fluids~~.

14. (Currently Amended) The device of claim + 13, wherein the diffuser element is substantially impermeable to biological fluids or components of biological fluids ~~selectively permeable to water~~.

15. -16. (Canceled)

17. **(Currently Amended)** The device of claim 1, wherein the elongate body comprises at least two outlets disposed within the diffusion space.

18. **(Currently Amended)** The device of claim 1, wherein said elongate body defines at least two passageways lumen within the elongate body.

19. **(Currently Amended)** The device of claim 1, wherein the elongate body passageway lumen is adapted for delivery of agent at a low volume rate.

20. **(Currently Amended)** A drug delivery system comprising:
the drug delivery and dilution device of claim 1, communicably operably attached to a drug reservoir.

21. **(Previously Presented)** The drug delivery system of claim 20, wherein the drug reservoir contains Baclofen.

22. **(Previously Presented)** The drug delivery system of claim 1, wherein said drug is delivered in microliter or submicroliter quantities per day.

23. (Canceled)

24. **(Currently Amended)** The method of claim 25, ~~claim 25~~, wherein the formulation is introduced into the inlet at a low volume rate.

25. (Currently Amended) A method for delivery of an agent to a delivery site in a subject, the method comprising the steps of:

implanting at the delivery site at least a distal portion of a ~~drug delivery and dilution~~ device, the device comprising:

an elongate body comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a ~~passageway~~ lumen in the elongate body, said lumen extending between the proximal and distal ends; and

a diffuser element operatively associated with the elongate body so as to define a diffusion space, wherein the elongate body distal end outlet is disposed in and in fluid communication with the diffusion space, wherein the diffuser element is drug-permeable and water-permeable so as to provide for dilution of a drug in the diffusion space and movement of drug out of the device is in fluid communication with the elongate body passageway; and

introducing into the elongate body inlet a drug at a first concentration[[],];

wherein said drug moves through the elongate body lumen passageway, out the elongate body outlet, and into the diffusion space, and further wherein water from the environment outside the device passes into the diffusion space through the diffuser element to dilute drug in the diffusion space wherein the water mixes with the drug, thereby diluting the drug to a second concentration within the diffusion space, and wherein said diluted drug then diffuses out through the diffuser element to exit the device at the delivery site in the subject, wherein the elongate body passageway is at least partially filled with an agent formulation prior to said implanting.

26. – 28. (Canceled)

29. (Previously Presented) The device of claim 1 wherein the diffuser element comprises a polymeric film.

30. (Previously Amended) The device of claim 29 wherein the diffuser element has a Diffusion Coefficient (DC) value in the range between 4.1×10^{-6} and $3.3 \times 10^{-5} \mu\text{g/cm/sec}$.

31. (Currently Amended) The device of claim 1, wherein the elongate body is drug-impermeable wherein the diffuser element is substantially impermeable to drug and selectively permeable to water.

32. (New) The method of claim 25, wherein the elongate body lumen is at least partially filled with a drug formulation prior to said implanting.